

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Jane P. Bearinger et al

Examiner: Gregory Anderson

Serial No.: 10/781,582

Art Unit: 3773

Filed: 02/17/2004

Attorney Docket No.: IL-11213

TITLE: SYSTEM FOR CLOSURE  
OF A PHYSICAL ANOMALY

Honorable Commissioner for Patents  
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

**APPELLANT'S REPLY BRIEF (37 C.F.R. § 1.192)**

This Reply Brief is submitted in response to the "Examiner's Answer" mailed June 24, 2009. One copy of the Reply Brief is being transmitted.

**STATUS OF CLAIMS**

The application as originally filed contained claims 1-35. The claims on appeal are claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35. The status of all the claims in the proceeding is: Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 are rejected. Claims 2, 3, 7, 8, 9, 10, 18, 22, 23, 24, 26, 27, 28, 29, 30, and 33 are cancelled.

## **GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

The March 9, 2009 Office Action stated two (2) grounds of rejection. The two grounds of rejection are summarized as follows:

**Grounds of Rejection #1** Claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans in view of Bleys.

**Grounds of Rejection #2** - Claims 6, 13, and 15 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans in view of Bleys and further in view of Duane.

### **REPLY TO EXAMINER'S ANSWER REGARDING GROUNDS #1**

(Claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 rejected under 35 U.S.C. § 103(a) as unpatentable over Evans in view of Bleys)

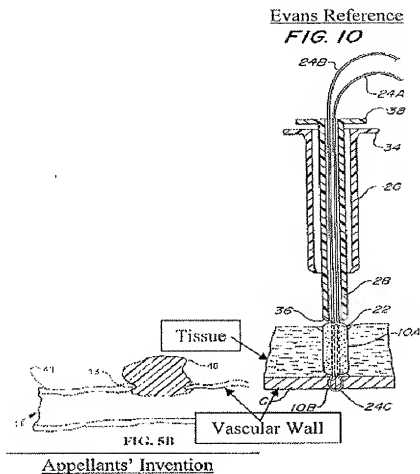
The Examiner's Answer contains the following statements in the last paragraph on page 5 and on the top of page 6:

"Appellant argues that Evans reference does not close a physical anomaly that forms a gap in a vascular wall. Examiner disagrees, while the foam of Evans et al does not close the gap in the vessel, the Evans et al device clearly does. The suturing aspect of the Evans et al device pulls the vessel walls together and is subsequently sealed by the insertion of the foam member. Further, the device of Evans et al is capable of being inserted within the vessel and if so placed would perform in the same manner as if it is placed slightly above the vessel in the overlying tissue as disclosed by Evans et al."

Appellants respectfully traverse these statements. The Evans reference percutaneous puncture site is located in the tissue outside the vascular wall and is not in the vascular wall itself as in Appellants' invention and claimed in Appellants' claims on appeal. The Evans reference states: "apparatus 20 is arranged to place the mass or body 22 either into the percutaneous puncture tract 10A or on the surface of the skin 12 above and contiguous with the puncture 10." (Col. 6, lines 9-11 of the Evans Reference) By contrast, Appellants' claimed

invention is an apparatus for closure of a physical anomaly that forms a gap in a vascular wall.

Differences between Appellants' claimed invention and the Evans reference are illustrated by the side by side comparison of FIG. 5B from Appellants' application and FIG. 10 from the Evans reference provided below.



Appellants' claimed invention is an apparatus for closure of a physical anomaly that forms a gap in a vascular wall. Appellants' claims include the claim limitations "deploy said closure body into the physical anomaly in the vascular wall" and "said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall" and "recovers its primary shape

with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly.” The Evans reference apparatus 20 is arranged to place the mass or body 22 into the percutaneous puncture tract 10A in the tissue or on the surface of the skin 12 in the tissue above the percutaneous puncture 10.”

Examiner’s Answer Does Not Meet Criterion 1

Appellants’ Appeal Brief pointed out many claim limitations of Appellants’ claims that are missing from the Evans and Bleys references. The Examiner’s Answer at the top of page 6 alleges that the Evans and Bleys references disclose all of Appellants’ claim limitations. Appellants list example of claim elements that are not shown by the Evans and Bleys references.

Claim 1

“An apparatus for closure of a physical anomaly that forms a gap in a vascular wall,” or

“said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above  $T_{trans}$  with a volume larger than the gap in the vascular wall,” or

“said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the  $T_{trans}$  with a volume smaller than the gap in the vascular wall,” or

“said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the  $T_{trans}$  so that it recovers its primary shape with a volume larger than the gap in the vascular wall,” or

“wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall,” or

“wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the  $T_{trans}$  so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly.”

Claim 5

"The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall."

**Claim 25**

"The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger.

**Claim 32**

"A system for the closure of a physical anomaly that forms a gap in a vascular wall," or

"a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam," or

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the  $T_{trans}$  with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," or

"said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall," or

"means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape;" or

"means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the  $T_{trans}$  so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly."

Since the identified claim limitations and elements are missing from the Evans and Bleys references, the Examiner's Answer and the Final Rejection do not meet Criterion 1 that the prior art references must teach or suggest all the claim limitations. Accordingly the rejection in Grounds of Rejection #1 should be reversed.

### Examiner's Answer Does Not Meet Criterion 2

The Examiner's Answer and the Final Rejection do not meet Criterion 2 that must be a reasonable expectation of success with the proposed combination.

The modification and combination proposed by the Examiner's Answer would defeat the operation of the apparatus and method disclosed in the Evans reference. The Evans reference apparatus and method requires that the loop 42 of the carrier filament 30 be anchored to the opening in the artery to pull the mass 22 into the percutaneous puncture tract 10A above the artery. This is illustrated in FIGS. 7 and 8 of the Evans reference reproduced below and described in Col. 7, lines 45-57 of the Evans reference reproduced below.

FIG. 7

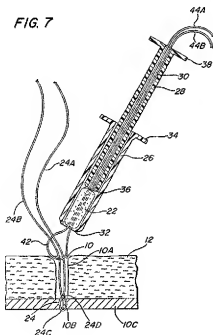
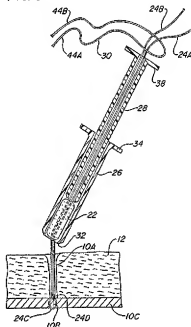
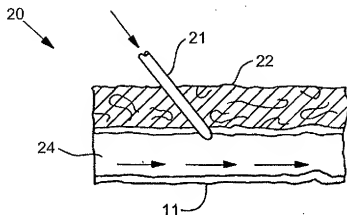


FIG. 8



The apparatus 20 is held by the user so that the loop 42 of the carrier filament 30 is adjacent the puncture tract like shown in FIG. 7, whereupon the extending portions 24A and 24B of the closure 24 are extended or passed through the interior of the loop by any suitable means (not shown). Once the extending portions 24A and 24B of the suture are passed through the carrier filament loop 42, the proximally extending portions 44A and 44B of carrier filament are pulled in the proximal direction. This action pulls the extending suture portions 24B and 24C through the passageway 40 of the mass 22, and through the interior of the tamper 28 until those extending portions are located proximally of the flanged end 38, as shown in FIG. 8.

It would be impossible to place the mass 22 of the Evans reference in the opening in the artery because there is no place to anchor the loop 42 of the carrier filament 30 to pull the mass 22 into the opening in the artery. This is better understood with reference to FIG. 2 of Appellants' application reproduced below.



**FIG. 2**

As shown by FIG. 2 of Appellants' application above, there is no place to anchor a loop of a carrier filament to pull a mass into the opening in the artery as required by the Evans reference.

Since the modification and combination proposed by the Examiner's Answer would defeat the operation of the apparatus and method disclosed in the Evans reference, Criteria 2 that there must be a reasonable expectation of success with the proposed combination has not been met and the rejection in Grounds of Rejection #1 should be reversed.

#### Examiner's Answer Does Not Meet Criterion 3

The Examiner's Answer contains the following statements on pages 4 and 5:

"It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al by using the shape memory foam of Bleys et al in order to provide a foam that exhibits good absorption and retention characteristics, good wicking properties, stability, and simplicity of

chemicals to ensure a minimum of leachable substances in contact with the human body as taught by Bleys et al.”

Appellants respectfully traverse these statements. The statements do not provide valid reasons why the Bleys reference would be combined with the Evans reference. The Evans reference discloses a “collagen foam” which is much different from Appellants’ claimed “shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above  $T_{trans}$  and said soft segment is formed at a temperature below  $T_{trans}$ ” The Examiner’s Answer statements that “It would have been obvious .. to modify the device of Evans et al by using the shape memory foam of Bleys et al in order to provide a foam that exhibits good absorption and retention characteristics, good wicking properties, stability, and simplicity of chemicals to ensure a minimum of leachable substances in contact with the human body” is not an obvious reason to modify the Evans reference. Criterion 3 requires that the Examiner provide reasons for combining the references to produce the proposed combination. Since the Examiner’s Answer and the Final Rejection do not meet Criterion 3, the rejection in Grounds of Rejection #1 should be reversed.

**REPLY TO EXAMINER’S ANSWER REGARDING GROUNDS #2**  
(Claims 6, 13, and 15 rejected under 35 U.S.C. § 103(a) as unpatentable over Evans in view of Bleys and further in view of Duane)

**Examiner’s Answer Does Not Meet Criterion 1**

The criterion that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. The Evans, Bleys, and Duane references fail to teach the following limitations of Appellants’ claims 6, 13, and 15:



Claim 6

“The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement.”

Claim 13

“The apparatus of claim 1 wherein said delivery device includes a backbleed tube.”

Claim 15

“The apparatus of claim 1 wherein said delivery device includes a delivery catheter, a plunger actuator, and a restraint tube.”

Since the identified claim limitations and elements are missing from the Evans reference and the Bleys and Duane reference, the Examiner’s Answer and the Office Action do not meet Criterion 1 that the prior art references must teach or suggest all the claim limitations. Accordingly the rejection in Grounds of Rejection #2 should be reversed.

Examiner’s Answer Does Not Meet Criterion 2

Since there are many claim elements missing from the Evans reference and the Bleys and Duane reference do not provide the missing claim elements, the Examiner’s Answer and the Office Action do not meet Criterion 2 that must be a reasonable expectation of success with the proposed combination. Accordingly the rejection in Grounds of Rejection #2 should be reversed.

Examiner’s Answer Does Not Meet Criterion 3

The Examiner’s Answer contains the following statements on page 6:

“it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al in view of Bleys et al with the restraint tube of Duane et al in order to provide backbleed control during and after placement of a catheter within a patient’s vascular system as taught by Duane et al. (Col. 2, lines 44-49)”

Appellants respectfully traverse these statements. The statements do not provide reasons why the Bleys reference and the Duane reference would be combined with the Evans reference.

The cited portion of the Duane reference, Col. 2, lines 44-49, is reproduced below for reference.

“There is a need for a device, heretofore unavailable, which provides backbleed control during and after placement of a monorail type catheter within a patient's vascular system, and which provides selective clamping of a guidewire for all varieties of catheters useful for diagnostic or treatment purposes.”

Appellants' claimed invention does not involve a “monorail type catheter” or “selective clamping of a guidewire” as specified in the cited portion of the Duane reference. Thus the cited portion of the Duane reference does not provide a valid reason why the Bleys reference and the Duane reference would be combined with the Evans reference.

Criterion 3 requires that the Examiner provide reasons for combining the references to produce the proposed combination. Since the Examiner's Answer and the Office Action do not provide such reason they do not meet Criterion 3 and the rejection in Grounds of Rejection #2 should be reversed.

**Summary**

Appellants' claims are unobvious over the references cited in the March 9, 2009 Office Action and the Examiner's Answer.

The rejection of Appellants' claims on appeal should be reversed.

It is respectfully requested that Appellants' claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal be allowed.

Respectfully submitted,

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Date: 7/2/2009